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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,816	09/25/2003	Vernon G. Wong	440882000201	6866

7590 06/24/2009  
Stephen Donovan Esq.  
2525 Dupont Dr., Mailstop T2-7H  
Irvine, CA 92614

EXAMINER
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FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1619

MAIL DATE	DELIVERY MODE
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06/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,816	<b>Applicant(s)</b> WONG ET AL.	
	<b>Examiner</b> SHANON A. FOLEY	<b>Art Unit</b> 1619	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35,37-39,42-47,51,52,93,94,96 and 97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35,37-39,42-47,51,52,93,94,96 and 97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/8/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1619, Examiner Foley.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2008 has been entered.

#### ***Specification***

The disclosure is objected to because of the following informalities:

In the "Definitions" section, there is a description provided for "infinite sink conditions". However, in the paragraph directly preceding Table 1, these conditions are referred to as "infinite snack" conditions.

It is also noted that there are two "Example 5" headings in the instant disclosure, see the headings preceding paragraphs [0096 and 0099] of the published version of the instant application (USPgPub 2004/0057979).

Appropriate correction is required.

#### ***Claim Objections***

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Claims 96 and 97 are objected to because of the following informalities: the claims recite the units, "um". This unit is presumably intended to recite "µm", as recited in the instant disclosure in example 5. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 37-39, 42-47, 51, 52, 93, 94, 96 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35, 39, 52 and 93 recite the language "at least about" to describe a percent of the anti-inflammatory agent that is released during a certain time period. If the agent were released at a rate slightly below the percentage recited, then the value would be "about" the percentage recited, but would not be "at least", which is also required by the claims. Applicant is required to clarify the language describing the release rate of the agent.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 96 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The claims state that the filament dimensions are between 650 and 790 mm and have a length of between 0.94 and **1.97** (emphasis added) “um” (which is probably intended to be “μm”). Applicant appears to have confused the units. Example 5 of the instant disclosure clearly recites that the filaments dimensions are between 650 and 790 μm and have a length of between 0.94 and **1.87** mm (emphasis added. Since the incorrect value and units are recited in the claims, new matter has been introduced.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35, 37-39, 42-47, 51, 52, 93, 94, 96 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. for reasons of record.

In response to the rejection of record, applicant compares the dimensions of the instant filaments with those of Wong et al. The conclusion of the calculations provided by applicant demonstrates that while the area/volume of Wong et al. is greater than that of the instant invention, the diameters and the release kinetics of the instant filaments compared with those of Wong et al. are substantially equal. From these calculations, applicant concludes that the instant implants “show surprising properties” because the implants of Wong et al. “would not provide drug concentrations in the vitreous levels described herein”.

However, this conclusion is unsupported from the comparison demonstrated by applicant. Applicant unequivocally shows that the diameters and the release rates of the

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filaments of the instant invention compared with those of Wong et al. are equal, despite the difference in area/volume differences. Applicant has not provided any evidence that would indicate that the vitreous release rates of Wong et al. would differ from those instantly claimed. On the contrary, given the similarity between the instant filaments and those of Wong et al., one of ordinary skill in the art at the time the invention was made would have concluded that the vitreous diffusion drug rates of Wong et al. would also be "substantially equal" to those instantly claimed. If the release rates of Wong et al. are substantially equal to those instantly claimed, why would the release rate differ in a vitreous environment? Applicant has provided no evidence to indicate that there would be a difference.

Even if supposing the release rates of the filaments of Wong et al. were different in a vitreous environment, Wong et al. clearly review routine techniques and reasons in the art for varying the release rates, depending on the disease to be treated, the progression or etiology exhibited, as well as the tolerability of the patient, see column 2, lines 36-42; column 4, lines 13-16; column 5, lines 1—37; column 6, lines 29-31 and column 7, lines 40-65.

Therefore, it is maintained that the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is

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(571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/  
Primary Examiner  
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